To be completed by Physician Adjudicator

Date Completed: ____________ (M/D/Y)
Adjudicator Code: ____________

Central Case No.: ____________
Case Copy No.: ____________

(For items 1-8, each question specifies “mark one” or “mark all” that apply.)

Complete Q1 - ECG, Q2 - cardiac enzyme, and Q3 - cardiac pain information for the following WHI Extension Study outcomes: Myocardial infarction (MI), coronary death [hospitalized], and coronary revascularization

1. ECG pattern: (Mark the one category that applies best.)
   - Evolving Q-wave and evolving ST-T abnormalities
   - Equivocal Q-wave evolution; or evolving ST-T abnormalities; or new left bundle branch block
   - Q-waves or ST-T abnormalities suggestive of an MI and not classified as code 1 or 2 above
   - Other ECG pattern, ECG uncodable, or normal ECG pattern
   - ECG not available

2. Cardiac enzyme information available?
   - No → Skip to Question 3 on page 2.
   - Yes

2.1. Serum creatine kinase (CK): (Mark all that apply.) (Always record % or index if available.)
   If CK-MB available:
   - CK-MB expressed as a % or index: (Record peak results only.)
     - CK-MB at least 2x upper limit of normal for % or index
     - CK-MB greater than upper limit of normal but less than 2x upper limit of normal for % or index
     - CK-MB within normal limits for % or index
   - CK-MB expressed in units (usually ng/ml): (Record peak results only.)
     - CK-MB at least 2x upper limit of normal for units
     - CK-MB greater than upper limit of normal but less than 2x upper limit of normal for units
     - CK-MB within normal limits for units
   If CK-MB not available:
   - Total CK at least 2x upper limit of normal
   - Total CK greater than upper limit of normal but less than 2x upper limit of normal
   - Total CK within normal limits
   - CK result not available
2.2. Troponin lab test. *(Mark the one category that applies best.)* *(If more than one test was conducted, record the type with the most elevated lab result.)*

- □ 1 Troponin C
- □ 2 Troponin I
- □ 3 Troponin T
- □ 4 Troponin, not specified
- □ 9 Troponin not available → **Skip to Question 3 below.**

2.2.1 Results *(Mark the one category that applies best.)* Troponin values should be coded using the upper limit of normal (ULN) and not upper limit of indeterminate/indecisive as the reference value. Thus, if 2 cutpoints are given, choose the lower cutpoint for the upper limit of normal.

- □ 1 Troponin at least 2x upper limit of normal
- □ 2 Troponin greater than upper limit of normal but less than 2x upper limit of normal
- □ 3 Troponin within normal limits
- □ 9 Other

3. Cardiac pain defined as: an acute episode of pain, discomfort or tightness in the chest, arm, throat or jaw: *(Mark the one category that applies best.)*

- □ 1 Present
- □ 2 Absent
- □ 9 Unknown/Not recorded

4. Definite, probable, or aborted myocardial infarction *(See excerpts from Table 8.5.1 – Definition of Criteria for Diagnosis of Myocardial Infarction and Table 8.5.2 – Algorithm for Enzyme Diagnostic Criteria on the last page of this form.)*

4.1. Date of admission: _______ - _______ - _______ (M/D/Y)

4.2. Diagnosis: *(Mark one.)*

- □ 1 Myocardial infarction not occurring as a result of or during a procedure → **Skip to Question 4.3 on the next page.**

- □ 2 Myocardial infarction during or resulting from a procedure, i.e., within 30 days of any procedure.

4.2.1. Type of Procedure *(Mark one.)*

- □ 1 A myocardial infarction that followed a cardiac procedure within 24 hours *(for example, diagnostic coronary catheterization, percutaneous coronary intervention, CABG, pacemaker insertion, or cardioversion).*

- □ 2 A myocardial infarction that followed a cardiac procedure within 2-30 days *(for example, diagnostic coronary catheterization, percutaneous coronary intervention, CABG, pacemaker insertion, or cardioversion).*

- □ 3 A myocardial infarction that followed a non-cardiac procedure within 30 days *(for example, any elective or emergency non-cardiac vascular procedure regardless of type of anesthesia, or any elective or emergency surgical procedure requiring more than local anesthesia).*
4.3 Was a thrombolytic agent administered or emergent* revascularization procedure (e.g., angioplasty or stent) performed? *(Mark one.)*

*An emergent revascularization is conducted within 12 hours of symptom onset; code both here and in Q6. Non-emergent revascularization procedures are coded only under Q6. Examples of thrombolytic agents are streptokinase, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase).

- □ 0 No
- □ 1 Yes
- □ 9 Unknown

4.4. Was the myocardial infarction fatal? *(Mark one.)*

- □ 0 No
- □ 1 Yes *(Complete Question 5 below [for hospitalized deaths only] and Form 124 - Final Report of Death.)*

For hospitalized deaths only:


5.1. Date of Death: __________ - __________ - __________ (M/D/Y)

5.2. Diagnosis: ____________________________________________________________

6. Coronary revascularization

6.1. Date of Admission/Procedure: __________ - __________ - __________ (M/D/Y)

6.2. Type of procedure: Any one of the following procedures aimed at improving cardiac status *(Mark all that apply.)*

- □ 1 Coronary artery bypass graft (CABG)
- □ 2 Percutaneous transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy

6.3. Second myocardial infarction (MI) (i.e., second MI not already reported in Question 4) occurring as a result of or during the revascularization procedure. *(Mark one.)*

- □ 0 No
- □ 1 Yes
- □ 2 Unknown
7. Carotid artery disease requiring and/or occurring during hospitalization. Disease must be symptomatic and/or requiring intervention (i.e., vascular or surgical procedure).

7.1. Date of Admission: [ ] - [ ] - [ ] (M/D/Y)

7.2. Diagnosis: (Mark one.)

- [ ] Carotid artery occlusion and stenosis without documentation of cerebral infarction
- [ ] Carotid artery occlusion and stenosis with documentation of cerebral infarction

7.3. Carotid artery disease based on (Hospitalization plus one or more of the following): (Mark all that apply.)

- [ ] Symptomatic disease with carotid artery disease listed on the hospital discharge summary
- [ ] Symptomatic disease with abnormal findings (≥ 50% stenosis) on carotid angiogram, MRA, or Doppler flow study
- [ ] Vascular or surgical procedure to improve flow to the ipsilateral brain

8. Peripheral arterial disease (aorta, iliac arteries, or below) requiring and/or occurring during hospitalization. Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene. Disease must be symptomatic and/or requiring intervention (e.g., vascular or surgical procedure for arterial insufficiency in the lower extremities or abdominal aortic aneurysm).

8.1. Date of Admission: [ ] - [ ] - [ ] (M/D/Y)

8.2. Diagnosis: (Mark the one category that applies best.)

- [ ] Lower extremity claudication
- [ ] Atherosclerosis of arteries of the lower extremities
- [ ] Arterial embolism and/or thrombosis of the lower extremities
- [ ] Abdominal aortic aneurysm (AAA)

8.3. Peripheral arterial disease based on: Defined by hospitalization plus one or more of the following: (Mark all that apply.)

- [ ] Ultrasoundographically- or angiographically-demonstrated obstruction, or ulcerated plaque (≥ 50% of the diameter or ≥ 75% of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below
- [ ] Absence of pulse by doppler in any major vessel of lower extremities
- [ ] Exercise test that is positive for lower extremity claudication
- [ ] Surgery, angioplasty, or thrombolysis for peripheral arterial disease
- [ ] Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene
- [ ] Exertional leg pain relieved by rest and at least one of the following: (1) claudication diagnosed by physician, or (2) ankle-arm systolic blood pressure ratio ≤ 0.8
- [ ] Ultrasoundographically- or angiographically-demonstrated abdominal aortic aneurysm
- [ ] Surgical or vascular procedure for abdominal aortic aneurysm

Responsible Adjudicator Signature
### Table 1
Definition of Criteria for Diagnosis of Myocardial Infarction

<table>
<thead>
<tr>
<th>ECG Pattern/Symptoms</th>
<th>Cardiac Enzyme Interpretation (see Table 8.8 below)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Abnormal</td>
</tr>
</tbody>
</table>

#### Cardiac pain present:

<table>
<thead>
<tr>
<th></th>
<th>Definite MI</th>
<th>Definite MI</th>
<th>Definite MI</th>
<th>Definite MI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evolving Q wave and evolving ST-T abnormalities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equivocal Q wave evolution; or evolving ST-T abnormalities, or new left bundle branch block</td>
<td>Definite MI</td>
<td>Definite MI</td>
<td>Probable MI</td>
<td>No MI</td>
</tr>
<tr>
<td>Q waves or ST-T abnormalities suggestive of an MI and not classified above</td>
<td>Definite MI</td>
<td>Probable MI</td>
<td>No MI</td>
<td>No MI</td>
</tr>
<tr>
<td>Other ECG, ECG absent or uncodable</td>
<td>Definite MI</td>
<td>No MI</td>
<td>No MI</td>
<td>No MI</td>
</tr>
</tbody>
</table>

#### Cardiac Pain absent:

<table>
<thead>
<tr>
<th></th>
<th>Definite MI</th>
<th>Definite MI</th>
<th>Definite MI</th>
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</tbody>
</table>

### Table 2
Algorithm for Enzyme Diagnostic Criteria

<table>
<thead>
<tr>
<th>Cardiac Enzyme</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Abnormal*</td>
</tr>
<tr>
<td>Creatine kinase MB fraction (CK-MB)</td>
<td>≥ 2x ULN (as %, index, or units); or “present” without quantification</td>
</tr>
<tr>
<td>Toponin (C, I, or T)**</td>
<td>Troponin ≥ 2x ULN</td>
</tr>
<tr>
<td>Total creatine kinase (CK) (no MB available)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

ULN = upper limit of normal  
WNL = within normal limits

* If both CK-MB and Troponin are available, Troponin must be elevated to be considered abnormal, if only CK-MB is available, abnormal levels are enough to code enzymes as abnormal, i.e., WHI considers Troponin as the most accurate indicator of myocardial injury.

** Code Troponin levels using the ULN and not Upper limit of undeterminate/indecisive as the reference value. Thus, if 2 cut points are given, choose the lower cut point for the ULN.